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LDR spine A Passion for Innovation

AUG 10 2006

510(k) Summary
LDR Spine USA Easyspine® System

Lateral Polyaxial (LP) and LP Multiaxial Pedicle Screws
6 mm and 7 mm Diameters

1. Owner's Name & Address

LDR Spine USA
4030 West Braker Lane, Suite 360
Austin, TX 78759

Phone: (512) 344-3333
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2. Contact Person

James W. Burrows
Director of Clinical Marketing
LDR Spine USA
4030 West Braker Lane, Suite 360
Austin, TX 78759

Phone: (512) 344-3307
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3. Date 510(k) Summary Prepared: April 12, 2006

4. Trade Name: Easyspine® System
Common Name: Pedicle Screw Spinal System
Classification Name: Pedicle Screw Spinal System (21 CFR §888.3070, Product Codes MNI and MNH)

5. Legally Marketed Equivalent Predicate Device

K043094 – LDR Spine USA Easyspine System consisting of rods, connectors, and Standard and α pedicle screws.

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6. Device Description

Easyspine implants are single use devices for mono-and multi-segmental stabilization of the lumbar and thoracic vertebrae to promote fusion. The Easyspine System consists of sacral and pedicle screws, cross-connections, and rods of different rigidities. Specialized associated instrumentation is designed for implantation of these devices and for the distraction, compression or reduction of the lumbar and thoracic spine.

The implants are made of surgical titanium alloy Ti6Al4V (ASTM F-136-92). Instruments used to implant Easyspine® are made of medical grade stainless steel.

Both the Easyspine LP and Easyspine LP Multiaxial designs consist of various screws, rods, and connectors which are intended to provide temporary stabilization following surgery to fuse the thoraco-lumbar spine. The systems include side-loading screws which are offset as compared to the standard configuration. This offset allows separate rod tightening and polyaxiality locking. Additionally, the system facilitates conducting spondylolisthesis reduction by allowing bone screwing after rod tightening.

The lateral offset loading feature incorporated into the designs has not altered the fundamental technology of the predicate Easyspine pedicle screw system.

Operatively inserted implants serve to support the normal healing process. They are not intended to replace normal body structures, nor in cases of incomplete healing, to withstand the continually applied loading conditions.

7. Intended Use of the Device

The LDR Spine USA Easyspine System is a posterior, non-cervical, pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis (with objective evidence of neurologic impairment), trauma (i. e., fracture or dislocation), spinal stenosis, deformities or curvatures (i. e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

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8. Summary of Technological Characteristics

Feature	*Easyspine System w/ Ø6.0 mm, Ø7 mm LP & LP Multiaxial Screw*	*Easyspine System (K043094)*	Substantially Equivalent?
Indications for Use:	The LDR Easyspine® System is a posterior, non-cervical, pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis (with objective evidence of neurologic impairment), trauma (i. e., fracture or dislocation), spinal stenosis, deformities or curvatures (i. e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.	Same	YES
Design:	Posterior - pedicle screw/rod spine system	Same	YES
Sterile:	Implants supplied sterile Instruments supplied non-sterile	Same	YES
Implant Sterilization Methods:	Gamma radiation	Same	YES
Implant Shelf Life:	Five Years	Same	YES
Rod Diameter:	6 mm	Same	YES
Material:	Titanium Alloy Ti6Al4V	Same	YES
Screw Sizes:	6 and 7 mm Diameters	Same	YES
Manufacturer:	LDR Spine Medical	Same	YES
Product Code:	MNI, MNH	Same	YES

9. Non-Clinical Performance Data

Testing was conducted in accordance with *ASTM 1717-04 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.* Based upon the test data presented, risk analysis, and comparison of features, the LDR Spine 6 mm and 7 mm diameter Easyspine LP and LP Multiaxial screws are substantially equivalent to the LDR Spine 6mm and 7 mm diameter Easyspine Standard and Easyspine α pedicle screws that were cleared in premarket notification K043094.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2006

LDR Spine USA
% Mr. James W. Burrows
Director of Clinical Marketing
4030 West Braker Lane, Suite 360
Austin, Texas 78759

Re: K061017
Trade Name: Easyspine® System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH
Dated: July 19, 2006
Received: July 20, 2006

Dear Mr. Burrows:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K061017

Device Name(s): Easyspine® System

Indications for Use:

The LDR Spine USA Easyspine System is a posterior, noncervical, pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: spondylolisthesis (grades 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use X OR Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchholz for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061017

(Per 21 CFR 801.109) (Optional format 1-2-96)